APR 2 6 2001

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ABAXIS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K010670

1. Applicant Information:

Date Prepared:	March 5, 2001
Name:	Abaxis, Inc.
Address:	3240 Whipple Road Union City, CA 94587
Contact Person:	Amy Levin
Phone Number:	(510) 675-6517
Fax Number:	(510) 441-6150

2. Device Information:

Classification	Class II
Trade Name:	Piccolo® Chloride Test System

Classification Name:

Chloride test system	862.1170

3. Identification of legally marketed device to which the submitter claims equivalence:

The following table identifies the legally marketed device to which Abaxis claims equivalence:

Predicate Device			
Predicate Device	**Manufacturer**	**510(k) Number**	**Date of SE Determination**
Chloride Slides on the Vitros 950 Chemistry System	Johnson and Johnson Clinical Diagnostics	K800054	2/5/80

Summary of Safety and Effectiveness,

4. Description of the Device:

The Piccolo Electrolyte Reagent Disc (contains the Piccolo Chloride Test System) is designed to separate a heparinized whole blood sample into plasma and blood cells. The disc meters the required quantity of plasma and diluent, mixes the plasma with diluent, and delivers the mixture to the reaction cuvettes along the disc perimeter. The diluted plasma mixes with the reagent beads, initiating the chemical reactions that are then monitored by the analyzer. Alternately, the disc may also be used with serum.

5. Statement of Intended Use:

The Piccolo Electrolyte Reagent Disc (contains the Piccolo Chloride Test System) use with the Piccolo Point-of-Care Chemistry Analyzer is intended to be used for the *in vitro* quantitative determination of chloride in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.

6. Summary of the technological characteristics of the new device in comparison to those of the predicate device:

Table 1 outlines the technological characteristics of the Piccolo Chloride Test System in comparison to the legally marketed predicate device.

Specification Comparison: Piccolo Chloride Test System

	Piccolo Point-of-Care Chemistry Analyzer	**Vitros 950 Chemistry System**
Intended Use	Quantitative analysis of chloride	Quantitative analysis of chloride
Methodology	Enzymatic activation	Ion-selective electrodes
Sample Type	Heparinized whole blood, heparainized plasma, and serum	Heparinized plasma and serum
Sensitivity	80 mmol/L	50 mmol/L
Reagents	Dry test-specific reagent beads	Silver and silver chloride
Temperature	37°C	37°C
Calibration	Bar code with factory calibrated lot specific data	Calibrated periodically using calibrators supplied by vendor
Assay Range	80 -130 mmol/L	50 -175 mmol/L
Testing Environment	Professional use	Professional use
Sample Size	100 µL	10 µL

Summary of Safety and Effectiveness,

7. Brief discussion of the clinical and nonclinical tests relied on for a determination of substantial equivalence.

Tables 2 summarize the results of clinical and non-clinical tests performed using the Piccolo® Chloride Test System.

Linearity:

Data for chloride were found to be statistically linear at the 99% significance level by the F-test.

Table 2:
Summary of Linearity

	Chloride
F-Ratio	2.19
Slope	1.00
Intercept	0.00
Corr. Coefficient	0.98

(99% Critical F 2.62)

Precision:

Precision studies were designed to evaluate within-run and total precision of chloride included on the Piccolo® Electrolyte Reagent Disc when run on the Piccolo Point-of-Care Chemistry Analyzer.

Table 3:
Within-Run and Total Precision for Chloride,
Assayed on the Piccolo Point-of-Care Chemistry Analyzer

Analyte	Within-Run (n = 160)	Total (n= 160)
Chloride (mmol/L)		
Level 1		
Mean	97.8	97.8
SD	1.63	1.74
CV	1.7	1.7
Level 2		
Mean	113.6	113.6
SD	1.97	2.22
CV	1.7	2.0

Summary of Safety and Effectiveness,

Sample Type Comparison:

A study was conducted to examine to compare heparinized venous whole blood and serum on the Piccolo® Point-of-Care Chemistry Analyzer.

Serum and whole blood comparability were established for chloride.

8. Conclusions

The clinical and non-clinical tests performed for chloride, when run on the Piccolo Point-of-Care Chemistry Analyzer demonstrate that the test system is as safe, effective and performs as well as the legally marketed device identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 2 6 2001

Ms. Amy Levin
Regulatory Affairs Specialist
ABAXIS
3240 Whipple Road
Union City, CA 94587

Re: 510(k) NUMBER: K010670
Trade/Device Name: Piccolo® Chloride Test System
Regulation Number: 862.1170
Regulatory Class: II
Product Code: CHJ
Dated: March 5, 2001
Received: March 6, 2001

Dear Ms. Levin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

12.0 INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K010670

Device Name: **Piccolo® Chloride Test System**

Intended Use:

The Piccolo Chloride Test System (presently contained on the Electrolyte Reagent disc) used with the Piccolo Point-of-Care Chemistry Analyzer is intended to be used for the *in vitro* quantitative determination of chloride in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.

Indications for Use:

Chloride The chloride assay is used for the quantitiation of chloride in human heparinized whole blood, heparinized plasma or serum. Chloride measurements are used in the diagnosis and treatment of dehydration, prolonged diarrhea and vomiting, renal tubular disease, hyperparathyroidism, burns, salt losing renal diseases, overhydration, thiazide therapy.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010670

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ POC (Per 21 CFR 801.109) OR Over- The Counter Use _____ (Optional Format 1-2-96)